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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/254,407 02/07/00 GRADY

M JJM-399

EXAMINER

HM12/0723

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WHITE, E	
ART UNIT	PAPER NUMBER

1623

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DATE MAILED:

07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/254,407

Applicant(s)
GRADY et al.

Examiner
Everett White

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) ☐ Of the above, claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, and 15 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ A) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper Noted
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

1. The request for consideration filed June 11, 2001 has been received and entered into the record.
2. Claims 1-16 are pending in the case.
3. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

Finality Withdrawn

4. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. The second set of claims, Claims 1-16, has been considered in this Office Action. Changes to the second set of claims have also been carried out to reflect the changes presented in Applicants Amendment filed December 8, 2000 (Amendment A, Paper No. 7).

Unity of Invention

5. The instant application sets forth two inventions along with the claimed sulfated polysaccharide products that are directed to different methods of using the sulfated polysaccharide of Claim 1. See Claims 14-16. The first of the two invention (Claims 14 and 15) is considered in this office action. The second of the two invention (Claim 16) has been withdrawn from consideration. However, if the sulfated polysaccharide of Claim 1 is found to be allowable, the subject matter of Claim 16 may be rejoined with the rest of the claims. See PCT Article 17(3)(a) and 1.476(c).

IMPROPER MULTIPLE DEPENDENT CLAIMS

6. Claims 11-13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Changing the term "any" to --any one-- may over come this rejection.

35 U.S.C. 112, Second Paragraph Rejection

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 14, line 3, the phrase "composition of claim 1" lacks clear antecedent basis since claim 1 is drawn to a sulfated polysaccharide product. A composition is not indicated in Claim 1. Claim 15 is also rejected since Claim 15 depends from Claim 14.

35 U.S.C. 103 REJECTION

9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tunc (US Patent No. 3,709,877).

Applicants claim a sulfated polysaccharide selected from group consisting of sulfated cellulose derivatives and sulfated polyanionic polysaccharides.

The Tunc patent discloses cellulose sulfate produced by reacting together cellulose ethers and a sulfating agent wherein the cellulose ether used may be selected as hydroxypropyl cellulose which embraces the sulfated hydroxyethyl cellulose product disclosed in instant claim 2. The Tunc patent discloses the same cellulose ether compound except for a hydroxypropyl substituent rather than the hydroxyethyl substituent claimed by applicant. The claimed hydroxyethyl substituent is a homologue of the disclosed hydroxypropyl substituent. Homologues are a class of compounds differing only by a methylene linkage and possessing similar structures. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant(s) invention to replace the hydroxypropyl substituent of the cellulose ether of the Tunc patent with a homologue such as hydroxyethyl in view of their closely related structures and the resulting expectation of the cellulose ether compounds having similar packaging properties.

10. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easton (EP 140,596, already of record) in view of Tunc (US Patent No. 3,939,836, already of record).

Applicants claim a sulfated polysaccharide and pharmaceutical composition comprising the sulfated polysaccharide.

The Easton et al reference discloses a wound dressing having a wound contacting layer form from a complex that includes a biodegradable protein, or a proteolytic degradation product thereof, with a polyanionic plant polysaccharide. Easton et al further discloses that a surgical implant can be formed from the complex. Easton disclosed that the term "surgical implant" includes sutures, blood vessel grafts, artificial organs, soft tissue implants and prostheses (see page 2, 1st paragraph). Examples of the polyanionic plant polysaccharides disclosed in the Easton et al reference include alginates, carrageenans, celluloses such as carboxymethyl cellulose, xanthan gum and sulphate dextrans (see page 4, lines 21-34). Also see page 1, second paragraph of the Easton et al reference which sets forth a number of polyanionic polysaccharides that are well known in the art to be useful in a wide variety of medical and surgical applications which include hyaluronic acid, chondroitin 4-sulphate, chondroitin 6-sulphate, dermatan sulphate, keratan sulphate and heparan sulphate. The instant invention differ from the above description of a wound dressing having a wound contacting layer form from a complex that comprises a polyanionic plant polysaccharide by indicating that the polysaccharides are synthetic sulfated polysaccharides. However, the sulfation of polysaccharides is well known in the art. For example, see column 3, lines 18-38 of the Tunc patent wherein a well known procedure for preparing sulfated cellulose is disclosed. The Tunc patent shows that the use of sulfated cellulose in wound dressings is well known in the art. It would have been obvious to modify the polyanionic polysaccharides of the Easton et al reference by subjecting the polysaccharides thereof, to a sulfated procedure as taught by the Tunc patent, since the Tunc patent suggests at column 3, last paragraph, that by modifying the degree of sulfate substitution of the

polysaccharide, the salt resistance and water dispersibility of the bonded nonwoven fabric (when the polysaccharide is used in the form of a fabric) can be modified to provide fabrics which will function effectively when contacted by various body fluids - which may be flushed away in a water closet.

12. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

13. Claims 1-10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spilburg et al (U.S. Patent No. 5,679,375).

Applicants claim a sulfated polysaccharide, pharmaceutical composition thereof, and a method of treatment of medical conditions mediated by a matrix metalloproteinase which treatment comprises the application of sulfated polysaccharide composition.

The Spilburg et al patent discloses a composition for treating ulcers comprising an effective amount of high molecular weight sulfated polysaccharide having a sulfate to monomer ratio of from 1.0 to about 3.0 (see column 16, lines 10-15). The Spilburg et al patent does not mention medical conditions mediated by a matrix metalloproteinase. However, the treatment of ulcers that is mentioned in the Spilburg et al patent embraces the treatment of medical conditions mediated by a matrix metalloproteinase. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicants invention having the Spilburg et al patent before him to use a sulfated polysaccharide to treat medical conditions mediated by a matrix metalloproteinase such as ulcers as suggested in the Spilburg et al patent in view of their closely related sulfated polysaccharide used in the compositions thereof and the resulting expectation of similar therapeutic properties possess by the sulfated polysaccharides.

14. Applicant's arguments with respect to claims 1-10, 14 and 15 have been considered but are moot in view of the new ground(s) of rejection.

15. **Summary:** Claims 1-10, 14 and 15 are rejected; Claim 11-13 are objected to; and Claim 16 is withdrawn from consideration.

Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

White
July 18, 2001



GARY GEIST
SUPERVISORY PATENT EXAMINER
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